IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Barbara Forman, Individually and on behalf of others similarly situated,	:	
	:	Case No. 1:17-cv-774
Plaintiff,	:	
	:	Judge Susan J. Dlott
v.	:	
	:	Order Granting Motion for
Meridian Bioscience, Inc., *et al.*,	:	Reconsideration
	:	
Defendants.	:	

This matter is before the Court on Plaintiff's Motion to Reconsider, Set Aside, Alter, Amend, or Vacate Judgment pursuant to FRCP 59(e), 60(b)(1), and/or 60(b)(6) ("Motion to Reconsider") (Doc. 39) the Court's Order Granting Motion to Dismiss ("Dismissal Order") (Doc. 36). Plaintiff moves for reconsideration, in part, on the issue of whether she adequately pleaded scienter as to the alleged misrepresentation that all of the Magellan LeadCare products were FDA cleared. For the reasons that follow, the Court will **GRANT** the Motion for Reconsideration.

I. PROCEDURAL POSTURE

On April 16, 2018, Court-appointed Lead Plaintiff Barbara Forman filed an Amended Complaint against Defendants Meridian Bioscience, Inc. ("Meridian"), John Kraeutler, and Melissa Lueke "on behalf of herself and all other persons or entities who purchased or otherwise acquired securities of [Meridian] between March 24, 2016 and October 23, 2017." (Doc. 29 at PageID 172.) Plaintiff alleged generally that Meridian made misstatements about blood lead level testing systems manufactured by Magellan Biosciences, Inc. ("Magellan"), a company Meridian acquired in March 2016. She asserted two claims for relief:

> Count I: Violations of § 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against all Defendants; and
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> Count II: Violations of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against all Defendants.

(Doc. 29 at PageID 278–282.) Defendants then moved to dismiss the First Amended Complaint on the grounds that Plaintiff did not state a claim for relief under the standards set forth in the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(1). (Doc. 32.) The Court granted dismissal of Plaintiff's claims in the Dismissal Order. (Doc. 36.)

The Court will summarize the Dismissal Order to assist the analysis that follows. To begin, the Court recognized that Plaintiff alleged that Meridian had made misstatements about several issues, including the efficacy of the LeadCare products, its performance expectations for Magellan, the purported fact that Magellan was "a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning," and the effectiveness of its internal controls. (Doc. 36 at PageID 418–420.) However, the Court held that the only actionable misstatement was Meridian's statement in the November 2016 Form 10-K that "[e]ach of the diagnostic products currently marketed by us in the United States has been cleared by the FDA pursuant to the 510(k) clearance process or is exempt from such requirements." (Meridian November 2016 Form 10-K at 12; Doc. 29 at PageID 213; Doc. 36 at PageID 419, 425.) The Court explained that this statement gave at least a materially false impression:

> Plaintiff alleges that Meridian did not timely provide the FDA with its notices to customers to use incubations periods for venous blood samples, about changes to its package labeling to instruct about the incubation period, or about customer complaints. As such, Plaintiff alleges that the LeadCare systems were not FDA-cleared to use with an incubation period for venous blood samples. The Court agrees that the particular statement that all Magellan products were FDA cleared is actionable on the theory that it gave a materially false impression. *See Bondali v. YumA Brands, Inc.*, 620 F. App'x 483, 491–92 (6th Cir. 2015).

(Doc. 36 at PageID 425.)[1]

The Court then turned to the scienter analysis. The Court recognized that "scienter includes a knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." *Dougherty v. Esperion Therapeutics, Inc.*, 905 F.3d 971, 979 (6th Cir. 2018) (citation omitted). It stated that recklessness is defined in this context as a "highly unreasonable conduct which is an extreme departure from the standards of ordinary care ... akin to conscious disregard." *Id.* at 980 (citation omitted). To this explanation, the Court now will add that recklessness requires more than negligence or the mere "notice and opportunity to commit fraud," but it is a lower standard than "knowing misrepresentation or intent." *In re Comshare Inc. Secs. Lit.*, 183 F.3d 542, 550–52 (6th Cir. 1999).

The Court found that the second and sixth factors from *Helwig v. Vencor, Inc.*, 251 F.3d 540, 552 (6th Cir. 2001)[2]—a divergence between internal reports and external statements and a disregard of the most current factual information before making statements—supported a finding of scienter:

> The Court concluded above that Plaintiff adequately has pleaded that Meridian made actionable false representations that all of the Magellan products were FDA cleared in the November 2016 Form 10-K. Plaintiff pleaded that in doing so Magellan and Meridian disregarded internal documents demonstrating problems with the LeadCare systems when using venous samples such as the September 2013 Reagent Study, CAR 108 opened in November 2014, the labeling changes to include an incubation period, the November 2016 notice to customers and product bulletin, and the customer complaints over several years. These internal documents suggest that an incubation period was required to achieve accurate results, but the FDA had not cleared LeadCare systems with the use of an incubation period.
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> To the extent that these Magellan documents were created or received prior to the acquisition by Meridian, Plaintiff has pleaded that the documents would have

[1] The Court should not have stated that Plaintiff did not dispute that this statement was literally true. (Doc. 36 at PageID 425.) Plaintiff alleged in the Amended Complaint that the statement was "materially false and misleading when made." (Doc. 29 at PageID 213–214.)

[2] R*ecognized as overruled in part on other grounds in Frank v. Dana Corp.*, 547 F.3d 564, 571 (6th Cir. 2008).

> been made available to Meridian during the due diligence process. Plaintiff also pleaded that Winslow, the former Magellan president and CEO who became an executive vice-president and the head of the Magellan business unit for Meridian, participated in monthly "flash calls" with other Meridian executives to discuss monthly performance and outlook. Plaintiff specifically pleaded that customer complaints would have been discussed in these conference calls. The Court finds that the allegations are specific enough to withstand a Rule 12(b)(6) challenge. The second and sixth *Helwig* factors favor a finding that scienter exists. Such divergence between internal documents and public reports can be a "key factor" to finding scienter. *Dougherty*, 905 F.3d at 981.

(Doc. 36 at PageID 432–433.) The Court also found, however, that the remaining *Helwig* factors, and the non-*Helwig* factors suggested by Plaintiff, did not support scienter. (*Id.* at PageID 432–435.)

Finally, the Court examined Plaintiff's overarching theory of liability, but found that it was not as credible as Meridian's non-culpable explanation for the alleged misstatements:

> Plaintiff alleges that Meridian knowingly acquired a company facing serious regulatory problems, including a likely FDA product recall, to ameliorate its weakening financial position. Specifically, Plaintiff alleges that Meridian faced difficulties in its core diagnostic 2016 business unit because (1) its illumigene product was not performing as well as expected, (2) it was going to lose the patents for its *H. pylori* products in May 2016, and (3) it had a small research and development budget. Therefore, Plaintiff alleges, Meridian acquired Magellan to provide it with new diagnostic products and new growth driver. However, Plaintiff also alleges that Meridian knew that Magellan was facing serious regulatory problems, including a likely FDA product recall, because Magellan fraudulently was concealing the fact that its LeadCare products could not provide point-of-care accuracy without the use of an incubation period for venous blood samples.
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> Meridian contends this overall theory is nonsensical. Meridian asks why it would seek to boost it revenues and stock prices by acquiring a company with regulatory liabilities that would imperil its future prospects. Meridian asserts that it is more likely that Meridian believed that the acquisition of Magellan in fact would bolster its bottom line. Meridian does not dispute that it faced business difficulties prior to the acquisition of Magellan in early 2016. Meridian knew that Magellan's LeadCare products had been FDA cleared for use with capillary and venous blood samples and that the use of the products with capillary blood samples accounted for the majority of Magellan's revenues. Additionally, while Plaintiff has alleged that Meridian knew or should have known that Magellan had made changes to LeadCare's labeling and instructions without timely informing the FDA, there is no allegation that Meridian would have known that the use of an

> incubation period did not ameliorate the underestimation problem for venous blood samples. Meridian did not receive customer complaints about problems with incubated samples until January 2017. Therefore, Meridian's purportedly misleading, but literally true, statement in November 2016 that all of Magellan's LeadCare systems were FDA cleared likely was not made with knowing, deliberate, or reckless intent to deceive investors.
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> Plaintiff's theory of liability is not as compelling as Meridian's non-culpable explanation. As such, the Court concludes that Meridian's specific statement in November 2016 that all of its products were FDA cleared does not rise to the level of "a knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." *Dougherty*, 905 F.3d at 878 (citation omitted).

(Doc. 36 at 436–438.)

In the Motion for Reconsideration, Plaintiff asserts that the Court erred when it concluded that she did not adequately plead scienter regarding the alleged misrepresentation in the 2016 Form 10-K that all LeadCare products were FDA cleared. Meridian responds that the Court did not err, and it urges the Court to deny the Motion for Reconsideration.

II. STANDARD OF LAW

Motions for reconsideration are treated as motions to amend a judgment pursuant to Rule 59(e) of the Federal Rules of Civil Procedure. There are three grounds for amending a judgment pursuant to Rule 59(e): "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at the time of trial; and (3) to correct a clear error of law or to prevent manifest injustice." *Berridge v. Heiser*, 993 F. Supp. 1136, 1146–47 (S.D. Ohio 1997); *see also GenCorp, Inc. v. American Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999) (same). Resolution of a motion for reconsideration is within the discretion of the district court. *Cline v. City of Mansfield*, 745 F. Supp. 2d 773, 841 (N.D. Ohio 2010), *aff'd*, *Cline v. Myers*, 495 F. App'x 578 (6th Cir. 2012). The term "clear error" is not well-defined in the Sixth Circuit, but it does "clearly indicate[] that a high standard applies." *Lonardo v. Travelers Indem. Co.*, 706 F. Supp. 2d 766, 809 (N.D. Ohio 2010), *on reconsideration in part* (July 21, 2010). The

manifest injustice inquiry is "a fact-specific analysis that falls squarely within the discretionary authority of the Court." *Id.*

Likewise, Rule 60(b)(1) authorizes a district court to grant relief from a final judgment for "mistake, inadvertence, surprise, or excusable neglect," while Rule 60(b)(6) authorizes it for "any other reason that justifies relief." Fed. R. Civ. P. 60. Rule 60(b)(1) is "intended to provide relief to a party in only two instances: (1) when the party has made an excusable litigation mistake or an attorney in the litigation has acted without authority; or (2) when the judge has made a substantive mistake of law or fact in the final judgment or order." *Cacevic v. City of Hazel Park*, 226 F.3d 483, 490 (6th Cir. 2000) (citation omitted). Courts apply Rule 60(b)(6) only in exceptional or extraordinary circumstances which are not addressed by the first five numbered clauses of the Rule. *See Gonzalez v. Crosby*, 545 U.S. 524, 536 (2005); *Pierce v. United Mine Workers of America Welfare and Retirement Fund for 1950 and 1974*, 770 F.2d 449, 451 (6th Cir. 1985). However, a district court's discretion in considering a motion made under Rule 60(b)(6) is "especially broad" given the underlying equitable principles involved. *Hopper v. Euclid Manor Nursing Home, Inc.*, 867 F.2d 291, 294 (6th Cir. 1989).

III. ANALYSIS

The Court agrees with Plaintiff that it misapplied the scienter standard to the narrow question before the Court. This constituted either a clear error creating a manifest injustice under Rule 59 or a substantive mistake of law or fact under Rule 60. First, the Court's scienter analysis focused too much on Meridian's non-culpable explanation for its decision to purchase Magellan. The Court found compelling Meridian's argument that it would not have made sense for it to knowingly acquire a company with regulatory liabilities when its goal was to boost its revenues and stock prices. However, this argument is not directly responsive to the more specific issue of

whether Meridian acted recklessly *eight months after it acquired Magellan* when it stated in the November 2016 Form 10-K that all of its products were FDA cleared. The Court finds upon reconsideration that Meridian made the misstatement in November 2016 with scienter.

Even apart from what Meridian should have learned about labeling changes and underestimation issues during the pre-acquisition due diligence process, during the post-acquisition period, Magellan issued a notice and a product bulletin to customers in early November 2016 telling customers to implement a four-hour incubation period for venous blood samples on the LeadCare II system. (Doc. 29 at PageID 223, 261.) On November 17, 2016, Meridian opened an engineering change order to revise the label for LeadCare II to include the four-hour incubation period. (*Id.* at PageID 206, 261.) Despite the fact that Meridian knew that the labeling change required a 510(k) submission, Meridian did not report this label change to the FDA. (*Id.* at PageID 206.) Magellan tried to send a medical device report ("MDR") to the FDA regarding the underestimation issue for the LeadCare II system in November 2016, but it was returned by the FDA for being submitted in the wrong format. Yet, Magellan did not re-submit the MDR to the FDA until six months later in May 2017. (*Id.* at PageID 224, 261.)

As alleged in the Amended Complaint, an FDA premarket notification submission was required not only for the initial distribution of a product to the market, but also for significant modifications in the intended use of a product. (*Id.* at PageID 198 (citing 21 C.F.R. § 807.81).) The change in labeling and instruction for use was a significant modification. Nonetheless, Meridian recklessly and misleadingly stated in its November 2016 Form 10-K that all of its products, including all of the LeadCare products, were "cleared by the FDA." (Meridian November 2016 Form 10-K at 12; Doc. 29 at PageID 213.) The Court reiterates its previous

conclusion that the allegations in the Amended Complaint satisfy the second and sixth *Helwig* factors and are a key factor supporting a finding of scienter.

Second, the Court erred in the Dismissal Order by conflating two separate issues in the scienter analysis: (1) the efficacy of the LeadCare products and (2) the FDA clearance requirement. The Court emphasized that "there is no allegation that Meridian would have known [prior to January 2017] that the use of an incubation period did not ameliorate the underestimation problem for venous blood samples." (Doc. 36 at 437.) While the issues of efficacy and FDA clearance may overlap, they are not the same.[3] The Sixth Circuit has described the 510(k) premarket clearance process as "a streamlined process" that is focused on equivalence to another product on the market, and that "does not comment on safety." *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 573–74 (6th Cir. 2012). As stated above, an FDA premarket notification submission was required for significant modifications in the intended use of a product. (Doc. 29 at PageID 198 (citing 21 C.F.R. § 807.81).) The Court should not have used the inference that Meridian believed that an incubation period would ameliorate the underestimation problem to support a finding that Meridian did not act with scienter when it stated that all LeadCare products were FDA cleared. When the Court examines the scienter question without giving undue emphasis to Meridian's reasons for acquire Magellan in early 2016, and without conflating efficacy with FDA clearance, the Court concludes that Plaintiff has adequately pleaded that Meridian acted with scienter in November 2016 when it stated that all of its products were FDA-cleared.

[3] In fact, Plaintiff alleges that even when Meridian did receive complaints in January 2017 about the underestimation of blood lead levels for the LeadCare Ultra system despite using the incubation period, Meridian failed to notify the FDA. (Doc. 29 at PageID 206, 231.) This can be read to suggest that Meridian was not overly concerned with either safety and efficacy of the LeadCare products or with complying with FDA regulations.

IV. CONCLUSION

For the reasons that follow, the Plaintiff's Motion for Reconsideration (Doc. 39) is **GRANTED**. Further, Defendants' Motion to Dismiss (Doc. 32) is **DENIED IN PART** to the extent that Plaintiff has based her claims on the allegedly misleading statement in the November 2016 Form 10-K that all of Meridian's products were FDA cleared or exempt from the clearance process.

IT IS SO ORDERED.

Dated this 20th day of May, 2019.

BY THE COURT:

S/Susan J. Dlott
Susan J. Dlott
United States District Judge